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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,790	11/12/2003	Gerald B. Pier	B0801.70255US01	5867
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WOLF GREENFIELD & SACKS, PC FEDERAL RESERVE PLAZA 600 ATLANTIC AVENUE BOSTON, MA 02210-2206				
			EXAMINER DEVI, SARVAMANGALA J N	
			ART UNIT 1645	PAPER NUMBER

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/713,790

Applicant(s)

PIER ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28, 42, 45, 60-62, 66, 68, 78 and 82 ~~is~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-28, 42, 45, 60-62, 66, 68, 78 and 82 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Restriction

- 1) Claims 3, 7-14, 16-18, 20, 21, 26-28, 42, 45, 60-62, 66 and 68 have been amended.
Claims 29-41, 43, 44, 46-59, 63-65, 67, 69-77, 79-81 and 83-85 have been canceled.
Claims 1-28, 42, 45, 60-62, 66, 68, 78 and 82 are under prosecution.
- 2) Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-25 and 42, drawn to a composition comprising an isolated polysaccharide comprising beta-1,6-glucosamine polymer, a conjugate thereof, and a composition comprising the same, classified in class 514, subclass 23
 - II. Claim 26, drawn to a method of making an isolated polysaccharide having beta-1,6-glucosamine polymer comprising digesting a crude polysaccharide with lysozyme, classified in class 435, subclass 173.2
 - III. Claims 27 and 28, drawn to a method of making an isolated polysaccharide comprising beta-1,6-glucosamine polymer comprising incubation with hydrofluoric acid, classified in class 536, subclass 127
 - IV. Claim 45, drawn to a method for treating or preventing a staphylococcal infection comprising administering an isolated polysaccharide comprising beta-1,6-glucosamine polymer, classified in class 424, subclass 831
 - V. Claims 60-62, drawn to a method for generating antibodies specific for an isolated polysaccharide comprising beta-1,6-glucosamine polymer, classified in class 436, subclass 547
 - VI. Claim 66, drawn to a method of identifying a monoclonal antibody specific for a polysaccharide, classified in class 435, subclass 7.1
 - VII. Claim 68, drawn to a composition comprising an isolated binding agent that binds to an isolated polysaccharide comprising beta-1,6-glucosamine polymer, classified in class 530, subclass 387.5
 - VIII. Claim 78, drawn to a method of identifying the presence of a bacterial polysaccharide in a sample using an isolated binding agent, classified in class 435, subclass 7.2
 - IX. Claim 82, drawn to a method for treating a subject having a staphylococcal

infection comprising administering an isolated binding agent that binds to an isolated polysaccharide comprising beta-1,6-glucosamine polymer, classified in class 424, subclass 243.1

3) The polysaccharide composition of invention I and the binding agent composition of invention VII are structurally distinct from each other. While a polysaccharide is made of saccharide units, a binding agent such as an antibody is a glycoprotein which includes IgG comprising 2 heavy and 2 light chains containing constant and variable regions, including framework regions that act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. The two products require separate individual structural searches. Searching inventions I and VII together would impose a serious search burden. In the instant case, searches for the polysaccharide and the binding agent molecules are not coextensive.

4) Inventions I and IV, and inventions VII and IX, are related as product and process of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the polysaccharide composition of invention I and the binding agent composition of invention VII can be used in a materially different process, for example, as coating reagents in *in vitro* diagnostic assays.

5) Inventions VII and VIII are related as product and process of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the binding agent composition of invention VII can be used in a materially different process, for example, as a therapeutic agent in the treatment of staphylococcal infections.

Searching the inventions of inventions I and IV, inventions VII and IX, and inventions VII and VIII together would impose a serious search burden. These inventions have a separate status in the art as shown by their different classification/subclassification. The search for inventions IV, IX and VIII would require a text search for the claimed methods in addition to a

search for each product used therein. Moreover, even if each product were known, the methods, which use the products, may be novel and unobvious in view of the preamble or active steps.

6) Inventions II-VI, VII and IX are drawn to distinct methods which differ from one another in the method steps, parameters and product(s) used therein, method objectives, and/or ultimate goals accomplished. Therefore, searching the above-identified inventions together would involve non-coextensive searches and thus impose a serious search burden.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification/sub classification and divergent subject matter, and because the search required for each group is not required for the other groups, and since each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

7) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed. 37 CFR 1.143.

8) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

9) The Office has required restriction between product and process claims. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. 1.116; amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

Serial Number: 10/713,790
Art Unit: 1645
July 2006

examined for patentability in accordance with 37 C.F.R 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103 and 112. Until an elected product is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See 'Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C § 103(b),' 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right rejoinder.*

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply wherein the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

10) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number (571) 273-8300, which receives facsimile transmissions 24 hours a day and 7 days a week.

11) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

12) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Serial Number: 10/713,790
Art Unit: 1645
July 2006

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

July, 2006


S. DEVI, PH.D.
PRIMARY EXAMINER